5/14/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
T1754M

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

April 28, 1998

Ref: 98-DAL-WL-#40

WARNING LETTER

VIA FACSIMILE
AND FEDERAL EXPRESS

Mr. Raymond Hannigan
President and Chief Executive Officer
Kinetic Concepts, Inc.
8023 Vantage
San Antonio, Texas 78230-4726

Dear Mr. Hannigan:

During an inspection of your firm located in San Antonio, Texas, in September/October, 1997, investigators determined that your firm manufactures AC powered physical medicine beds, mattress overlays and external pneumatic compression devices. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the previous 1978 Good Manufacturing Practice (GMP) Regulations and the 1997 Quality System Requirements, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

> Failure of the quality assurance program to identify, recommend, or provide solutions for quality assurance problems and verify the implementation of such solutions, as required by 21 CFR 820.20. (1978 GMP citation) For example: incidents of charger malfunctions in 1996 and 1997 on the Transportair device.
>
> Failure to keep a written record, including conclusions and follow-up, of the investigation of any failure of a device to meet performance specifications after the device has been released for distribution, as required by 21 CFR 820.198. (1978 GMP citation) For example: complaint files reviewed involving the Transportair devices did not always include evidence of QA evaluation. A review of these records revealed that QA did not document an evaluation of each complaint.

Additionally, the inspection revealed that your devices are misbranded under Section 502(t)(2) in that information required to be submitted to the Food and Drug Administration (FDA) or by the Medical Device Reporting (MDR) regulation specified in 21 CFR Part 803 was not submitted as follows:

> Reports that Transportair batteries overcharged and/or released sulfuric acid fumes concern a malfunction that could cause or contribute to a death or serious injury if the malfunction were to recur. The following events are considered reportable:
>
> - 04/11/97 event, serial number [redacted]
> - 03/04/96 event, serial number [redacted]
> - 03/28/96 event, serial number [redacted]
> - 05/01/96 event, serial number [redacted]
> - 06/25/96 event, serial number [redacted]
> - 07/19/96 event, serial numbe [redacted]
> - 09/30/96 event, serial numbe [redacted]
> - 10/3/96 event, serial number [redacted]
> - 10/7/96 event, serial numbe [redacted] (site not identified), [redacted]
> - 02/18/97 event, serial numbe [redacted]

- 04/21/97 event, serial number [redacted]

- 05/05/97 event, serial number [redacted] (site not identified), [redacted].

- 05/07/97 event, serial number [redacted]

- 05/29/97 event, serial number [redacted]

Written MDR reports for the above listed incidents are to be submitted within 15 working days of receipt of this letter. If these reports cannot be submitted within that time period, you should provide this office with a response which indicates when the reports will be submitted. The MDR reports should reference this Warning Letter and be directed to:

Victoria A. Schmid
Reporting Systems Monitoring Branch (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

The MDR reporting requirements will be satisfied by the submission of a written report alone for the serious injury report described above. However, you are reminded that for death or serious injury reports other than that described above, your firm is obligated to file both the 5-day telephone alert and the 15-day written report.

Your response letter dated November 20, 1997, to the FDA-483, has been reviewed and does not adequately address corrective actions and solutions for the continuing problems at your firm on MDR reporting. Your reasons for not reporting MDR reports does not take into account members of patient populations, such as the critically ill, heavily sedated, immobile, unconscious or semi-conscious. These patients would not be capable of removing themselves from the presence of noxious fumes and odors. In addition, individuals in an elevator could not remove themselves in a timely fashion should an incident occur.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at

the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's quality assurance system relative to the requirements of the device Quality System Regulations. You should also submit a copy of the consultant's report, and certification by your firm's most responsible individual that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant. The certification of audit and corrections should be submitted to this office by August 30,1998.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Your response should be directed to Gwendolyn Sue Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely

Joseph R. Baca
Dallas District Director

Enclosure

cc: Dennis Noll
General Counsel and Vice President of Quality

William H. Quirk
Director of Regulatory Affairs

Richard L. Crawford
Director of Manufacturing
4958 Stout Dr.
San Antonio, TX 78219